4128. Adulteration and misbranding of Carbolatum salve. U. S. v. 193 Jars, etc. (F. D. C. No. 34612 Sample Nos. 3020-L, 3021-L.)

LIBEL FILED: January 26, 1953, District of Columbia.

ALLEGED SHIPMENT: On or about June 11, July 23, and August 11, 1952, by the Windsor Chemical Laboratories, from Philadelphia, Pa.

PRODUCT: 193 4-ounce jars and 165 14-ounce jars of *Carbolatum salve* at Washington, D. C. Analysis showed that the product in the 4-ounce jars contained not more than 1.55 percent of phenol and that the article in the 14-ounce jars contained not more than 0.67 percent of phenol. The National Formulary specifies that carbolic acid ointment contains not less than 1.8 percent of phenol.

LABEL, IN PART: (Jar) "Fleming's Carbolatum Salve for Man and Beast * * * Instructions: Carefully sooth injured member with warm water and apply Carbolatum twice a day as required. * * * For skin irritation mix one part Sulphur with four parts Carbolatum and use daily."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Carbolic Acid Ointment," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since it contained a smaller proportion of phenol than the minimum specified in the National Formulary.

Misbranding, Section 502 (a), the following label statements were false and misleading since the article was not an effective treatment for such conditions: "Carbolatum * * * soothes skin surface pains. For skin irritation mix one part Sulphur with four parts Carbolatum and use daily. For The Family A Great aid for * * * Bruises * * * and Irritated Skin * * * For Animals Skin Eruptions * * * Cow Pox." Further misbranding, Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against unsafe dosage and methods of application, in such manner and form, as are necessary for the protection of users since it contained phenol; and the labeling of the article failed to bear a warning against application to large areas of the body or against its use under a bandage on fingers or toes.

DISPOSITION: June 2, 1953. Default decree of condemnation. The court ordered that the product be delivered to a local hospital for its use and not for sale. The product was to be used in the maintenance department of the hospital, for machinery lubrication.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4129. Adulteration and misbranding of Cal-D-Fer tablets and tablets of mannitol hexanitrate with phenobarbital and adulteration of triple sulfa tablets. U. S. v. Shaw Pharmacal Co. Plea of guilty. Fine, $800. (F. D. C. No. 33766. Sample Nos. 11202-L, 12527-L, 31191-L.)

INFORMATION FILED: March 19, 1953, Eastern District of Missouri, against the Shaw Pharmacal Co., a corporation, St. Louis, Mo.

*See also No. 4128.

ALLEGED VIOLATION: On or about August 15 and September 17, 1951, the defendant caused a number of *Cal-D-Fer tablets* and *triple sulfa tablets* to be introduced and delivered for introduction into interstate commerce, at St. Louis, Mo., for delivery into the State of Ohio.

On or about May 22, 1951, the defendant gave to a firm engaged in the business of shipping drugs in interstate commerce, at St. Louis, Mo., an invoice containing a guaranty to the effect that no article listed in the invoice was adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On or about May 22, 1951, the defendant caused to be delivered to the holder of the guaranty, at St. Louis, Mo., a number of *tablets of mannitol hexanitrate with phenobarbital*, which were covered by the guaranty and which were adulterated and misbranded.

NATURE OF CHARGE: *Cal-D-Fer tablets.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess in that each tablet of the article was represented to contain 5 grains of calcium phosphate (dibasic), whereas each tablet of the article contained less than 5 grains of calcium phosphate (dibasic). Misbranding, Section 502 (a), the label statement "Each tablet contains * * * Calcium Phosphate (dibasic) 5 gr." was false and misleading.

Triple sulfa tablets. Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess in that the article was represented to supply to the body from each tablet 2.56 grains of sulfadiazine, 2.56 grains of sulfamerazine, and 2.56 grains of sulfamethazine, whereas the article would not supply to the body from each tablet such amounts of sulfadiazine, sulfamerazine, and sulfamethazine since the tablets would not completely disintegrate and thus part of each tablet would pass through the body, would be eliminated, and would not be used by the body.

Tablets of mannitol hexanitrate with phenobarbital. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each tablet was represented to contain ¼ grain of phenobarbital and ½ grain of mannitol hexanitrate, whereas each tablet contained less than ¼ grain of phenobarbital and less than ½ grain of mannitol hexanitrate. Misbranding, Section 502 (a), the label statement "Each tablet contains: Phenobarbital ¼ gr. * * * Mannitol Hexanitrate ½ gr." was false and misleading.

DISPOSITION: September 28, 1953. The defendant having entered a plea of guilty, the court fined it $800.

4130. Adulteration of iodophthalein, Ringer's solution tablets, ammoniated mercury ointment, and Atabrine Dihydrochloride, and adulteration and misbranding of quinine phosphate. U. S. v. 9,000 Bottles, etc. (F. D. C. No. 34914. Sample Nos. 43981–L, 43985–L, 43987–L to 43989–L, incl., 44151–L, 44155–L to 44158–L, incl., 44162–L, 44163–L.)

LIBEL FILED: March 30, 1953, District of Kansas.

ALLEGED SHIPMENT: During the month of August 1952, by Chemical Commodities, Inc., from Kansas City, Mo.

PRODUCT: 9,000 100-gram bottles of *iodophthalein*, 1,000 100-tablet bottles of *Ringer's solution tablets*, 2,000 1-pound jars of *ammoniated mercury ointment*, 33 4-ounce jars of *quinine phosphate*, and 23 pounds of *Atabrine Dihydrochloride* contained in 1 unlabeled drum but originally shipped in 4-ounce bottles, at Olathe, Kans.